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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Ryan P. Boucher

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IP Section

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EXAMINER

YANG, ANDREW

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

01/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/784,392	Applicant(s) BOUCHER ET AL.	
	Examiner ANDREW YANG	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to Applicants' amendment filed on 10/16/2008.

Claim Objections

Claim 1 is objected to because of the following informalities:

In claim 1, line 2, --member-- should be inserted after "first tubular".

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 and 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholten et al. (U.S. Patent No. 4969888) in view of Schiff (U.S. Patent No. 4467790) and further in view of Fogarty et al. (U.S. Patent No. 4483340).

Scholten et al. discloses a device for fixation of osteoporotic bone comprising a structure consisting of a balloon 76 and neck 77 with opposite ends spaced along an axis (Figure 22 and 23). The balloon 76 is inserted into the vertebral body via cannula 30 created by soft tissue expander 70 and inflated. As a result the balloon 76 compacts the bone marrow and moves the cortical bone (Figure 28) leaving a void or cavity to be treated (Column 7, Lines 17-21). The balloon 76 is then deflated and removed, at which

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time synthetic bone or methyl methacrylate cement is injected into the cavity. Scholten et al. fails to disclose wrapping the structure prior to insertion, unwrapping it after being inserted, then wrapping it once again before the structure is removed from the bone, wherein wrapping the structure includes causing differential rotation of one end of the structure about the axis relative to the other end. Schiff teaches a balloon 12 joined to a catheter at a proximal end, which is wrapped around a stylet 30 and then inserted percutaneously through sheath 40. Once in the operative position the balloon is untwisted and thus completing the insertion operation (Column 6, Lines 52-55). The balloon can then be removed upon completion of the procedure by deflating the balloon 12 and re-wrapping it and pulling it back through sheath 40. The balloon is twisted by rotating knob 28 in a clockwise direction with the balloon 12 held in place at location 50, while the tip 14 is gently rotated to assist with the wind (Column 5, Lines 60-64). The twisting significantly reduces the outer diameter of the balloon, making it extremely advantageous for percutaneous insertion through a small diameter sheath (Column 2, Lines 27-31). It would have been obvious to one skilled in the art at the time the invention was made to construct the balloon of Scholten et al. capable of being wrapped prior to insertion and removal in view of Schiff so that it would have the advantage of being able to fit through a sheath with a small diameter.

Scholten et al. and Schiff fail to disclose the claimed structural limitations of the balloon device for causing wrapping and unwrapping of the balloon member. Fogarty et al. teaches a balloon device 14 having a first tubular member 16 and a second tubular member 24 longitudinally extending through interior of the first tubular member and

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having a distal end 22 projecting outwardly beyond the distal end of the first tubular member. A stylet 30 extends longitudinally through the interior of the second tubular member 24 and having a distal end 32 anchored to the distal end 22 of the second tubular member 24. A structure 20 which is adapted to undergo expansion is secured to the distal end of the first tubular member 16 and has a second end secured to the distal end 22 of the second tubular member such that the structure substantially envelopes the distal end of the second tubular member 24. Rotating the stylet 30 causes the second tubular member 24 to rotate and thereby wrapping the balloon 20 around the longitudinal axis of the device (Column 2, Lines 59-65). An annular flow passage for expansion of the balloon 20 exists between the inner and outer tubes 24, 26 (column 2, lines 50-55). The stylet 30 is flexible, and wrapping of the balloon 20 causes it to elongate (Figures 3-4). The device of Fogarty et al. allows the balloon 20 to be more easily delivered to a given area within the body than devices with only a stylet for wrapping the balloon (Column 1, Lines 49-53). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Scholten et al. as modified by Schiff with the claimed structural limitations that allow for wrapping and unwrapping of the device in view of Fogarty et al. in order to more easily deliver the expandable structure to a certain within the body.

Response to Arguments

Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **ANDREW YANG** whose telephone number is (571)272-3472. The examiner can normally be reached on IFP.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew Yang/
Examiner, Art Unit 3775
1/4/2009

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733